



# UNITED STATES PATENT AND TRADEMARK OFFICE



UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.   | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------|------------------|
| 09/780,206  | 02/09/2001  | Michael Fritz        | RDID0028US            | 5556             |
| 48801   | 7590        | 08/12/2005           | EXAMINER              |                  |
| MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP<br>300 SOUTH WACKER DRIVE<br>SUITE 3200<br>CHICAGO, IL 60606 |             |                      | CHUNDURU, SURYAPRABHA |                  |
|   |             | ART UNIT             | PAPER NUMBER          |                  |
|   |             | 1637                 |                       |                  |

DATE MAILED: 08/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 09/780,206             | FRITZ ET AL.        |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Suryaprabha Chunduru   | 1637                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 29 December 2004.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 36-41 and 68-76 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 36-41 and 68-71 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

- efz/105*
- 4) Interview Summary (PTO-412)  
 Paper No(s)/Mail Date. \_\_\_\_\_
  - 5) Notice of Informal Patent Application (PTO-152)
  - 6) Other: \_\_\_\_\_

**Supplemental Action**

1. Upon reconsidering Applicants' request to consider the claim limitations, during the telephonic interview held on June 2, 2005, the previous office action is withdrawn and this supplemental action is made to address the issues raised in the interview.
2. Applicants' response to the office action filed on December 29, 2004 has been entered.
3. The IDS filed on June 7, 2004 and the Supplemental IDS filed on April 28, 2004 have been entered.
4. Claims 1-35, 42-67 are cancelled. Claims 36-41, 68-76 are pending.

***New Grounds of Rejections***

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an

international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

A. Claims 36-41, 69-76 are rejected under 35 U.S.C. 102(b) as being anticipated by Zanzucchi et al. (US 5,593,838).

Zanzucchi et al. teach an apparatus of 36, 70, for detecting nucleic acids in a sample (see col. 2, line 21-43, col. 4, line 15-62, Fig. 2) comprising

(a) a binding space for purifying nucleic acids by immobilizing the nucleic acids and separation of impurities (see col. 4, line 15-40, line 51-54, col. 5, line 50-60, Fig. 2-3, col. 6, line 51-58, Fig. 1B. wherein, Fig. 2-3 indicates a binding space (36) and Fig. 1B. indicates the collection of impurities);

(b) an amplification space for amplifying the nucleic acids wherein a part of amplification space is identical to a part of an amplification space (see col. 4, line 40-42, Fig. 1B and Fig. 2, indicating a part of a binding space includes an amplification space (40), said binding space and amplification space are connected through capillary channel (38));

(c) a detection space for detecting the nucleic acids (see col. 4, line 42-51, Fig. 2 indicating detection space (44)).

With regard to claims 37, 73, Zanzucchi et al. teach that the apparatus comprises reagents for purifying, amplifying and detecting the nucleic acid (see col. 9, line 15-33, col. 10, line 66, col. 12, line 42-60, col. 2, line 40-60);

With regard to claims 39, 41, 74, 76, Zanzucchi et al. teach that the amplification space comprises capillary space made up of glass (see col. 6, line 15-25, the microlaboratory disc

comprising amplification space is made up of glass, which acts as semiconductor, also see Fig. 5b, and col. 8, line 35-52, indicating complete capillary space is covered or made up of glass);

With regard to claim 40, 75, Zanzucchi et al. teach that the capillary space is a capillary reaction vessel surrounded by a heatable metal layer (see col. 6, line 59-67, metal layer indicates a heatable element);

With regard to claims 38, 69, Zanzucchi et al. teach that the detection space comprises at least part of the amplification space and the binding space, which facilitates transport of the sample and reagents through the binding space, amplification space and the detection space (see col. 4, line 35-54, indicating that the binding space, amplification space and detection space are interconnected to facilitate the flow of the fluids);

With regard to claims 71, Zanzucchi et al. teach that the binding space is defined by an inner surface of a reaction vessel, wherein the inner surface (adsorption filter element), that binds nucleic acids (see col. 9, line 15-33).

With regard to claim 72, Zanzucchi et al. teach a binding space for binding nucleic acids (see col. 9, line 15-33); reagents for amplifying and detecting the nucleic acids that bound to the surface (see col. 10, line 6-42, col. 12, 42-60); and a sample transport mechanism which transports the sample and reagents through the space (see col. 12, line 42-60, indicating plurality of modules on a microlaboratory space for sample transport) Thus the disclosure of Zanzucchi et al. meets the limitations in the instant claims.

B. Claims 36-41, 68-76 are rejected under 35 U.S.C. 102(e) as being anticipated by Yasuda et al et al. (US 6,093,370).

Yasuda et al. teach an apparatus of 36, 70, for detecting nucleic acids in a sample comprising

(a) a binding space for purifying nucleic acids by immobilizing the nucleic acids and separation of impurities (see col. 22, col. 9, line 5-27, Fig. 7 indicates DNA binding space (731 and 733), also Fig. 21-23 indicate binding space (431));

(b) an amplification space for amplifying the nucleic acids wherein a part of amplification space is identical to a part of an amplification space (see col. 9, line 27-36, col. 22, line 28-36, Fig. 7, indicates for amplification space (733), also see col. 17, line 11-27, Fig. 21-23, indicate amplification space (431));

(c ) a detection space for detecting the nucleic acids (col. 9, line36-40, col. 22, line 37-43, Fig.7 indicates detection space and analysis (732), also see col. 17, line 35-53, Fig. 23-24 indicates detection space (401, 444)).

With regard to claims 37, 73, Yasuda et al. teach that the apparatus comprises reagents for purifying, amplifying and detecting the nucleic acid (see col. 9, line 5-67, col. 10, line 23-53);

With regard to claims 39, 41, 74, 76, Yasuda et al. teach that the amplification space comprises capillary space made up of glass (see col. 16, line 24-48, Fig. 20-21);

With regard to claim 40, 75, Yasuda et al. teach that the capillary space is a capillary reaction vessel surrounded by a heatable metal (chromium) layer (see col. 16, line 33-36, Fig. 20-21);

With regard to claim 68, Yasuda et al. teach an apparatus comprising capillary reaction vessel surrounded by a single heatable metal layer wherein the layer is coated on the capillary

Art Unit: 1637

reaction vessel (see col. 16, 29-48, Fig. 20, 21, indicating a capillary tube coated with a metal layer, col. 23, line 11-34);

With regard to claims 38, 69, Yasuda et al. teach that the detection space comprises at least part of the amplification space and the binding space, which facilitates transport of the sample and reagents through the binding space, amplification space and the detection space (see col. 9, line 5-40, indicating that the binding space, amplification space and detection space are interconnected to facilitate the flow of the fluids);

With regard to claims 71, Yasuda et al. teach that the binding space is defined by an inner surface of a reaction vessel, wherein the inner surface (adsorption filter element), that binds nucleic acids (see col. 4, line 54-60, col. 9, line 5-40).

With regard to claim 72, Yasuda et al. teach that apparatus comprises a space for binding nucleic acids (see col. 4, line 54-60, col. 9, line 5-40); reagents for amplifying and detecting the nucleic acids that bound to the surface (see col. 9, line 5-67, col. 10, line 23-53); and a sample transport mechanism which transports the sample and reagents through the space (see col. 9, line 5-40, indicating 711, 712, 713 for sample transport inlets for transporting sample and reagent solutions). Thus the disclosure of Yasuda meets the limitations in the instant claims.

C. Claims 68 is rejected under 35 U.S.C. 102(e) as being anticipated by Anderson (USPN. 6,126,804).

Anderson teaches an apparatus of claim 68, for amplifying nucleic acids comprising a capillary reaction vessel (see col. 7, line 30-67, col. 8, line 1-4) surrounded by a single heatable metal layer wherein the layer is coated on the capillary reaction vessel (electrically conductive

coating made up of a metal, see col. 8, line 13-22). Accordingly the instant claim is anticipated by Andersen.

D. Claims 36-38, 69-73 are rejected under 35 U.S.C. 102(e) as being anticipated by Fields (US 2003/0027203).

Fields teaches an apparatus of 36, 70, for detecting nucleic acids in a sample (see page 2, paragraph 0022) comprising

- (a) a binding space for purifying nucleic acids by immobilizing the nucleic acids and separation of impurities (see page 2, paragraph 0027, page 4, paragraphs 0060-0061, Fig. 5);
- (b) an amplification space for amplifying the nucleic acids (see fig. 6, paragraph 0063) wherein a part of amplification space is identical to a part of an amplification space (see Fig. 6, wherein the vial 420 is connected to amplification space by capillary tubes);
- (c) a detection space for detecting the nucleic acids (see paragraphs 0063, indicates the amplified products are moved into device 425, for detection of amplified nucleic acid products).

With regard to claims 37, 73, Fields teaches that the apparatus comprises reagents for purifying, amplifying and detecting the nucleic acid (see page 3, paragraphs 0031-0034);

With regard to claims 38, 69, Fields teaches that the detection space comprises at least part of the amplification space and the binding space, which facilitates transport of the sample and reagents through the binding space, amplification space and the detection space (see Fig. 1-3 and Fig. 6, wherein the detection space comprises a part of amplification space and a part of the binding space connected by a 3-way and four-way connecting tubes facilitating transport of sample and reagents, page 3, paragraph 0049-0054);

With regard to claims 71, Fields teaches that the binding space is defined by an inner surface of a reaction vessel, wherein the inner surface (adsorption filter element), that binds nucleic acids (see page 4, paragraph 0061).

With regard to claim 72, Fields teaches that the apparatus comprises a space for binding nucleic acids (see page 2, paragraph 0027, page 4, paragraphs 0060-0061, Fig. 5); reagents for amplifying and detecting nucleic acids bound to the surface (see (see page 3, paragraphs 0031-0034); and a sample transport mechanism which transports the sample and reagent (see page 3, paragraph 0049-0054). Thus the disclosure of Fields meets the limitations in the instant claims.

***Response to arguments***

6. With regard to the objection to priority document maintained in the previous office action Applicants arguments, IDS submitted on June 7, 2004 and the English translation of German Patent Application No. DT 23 43 987 are considered and the objection is withdrawn herein.

7. With regard to the rejection made in the previous office action under 35 USC 112, second paragraph, Applicants arguments and amendment are fully considered and the rejection is withdrawn in view of the amendment.

8. With regard to the rejection made in the previous office action under 35 USC 102(b), Applicants arguments and amendment are fully considered and the rejection is withdrawn in view of the persuasive arguments.

***Conclusion***

No claims are allowable.

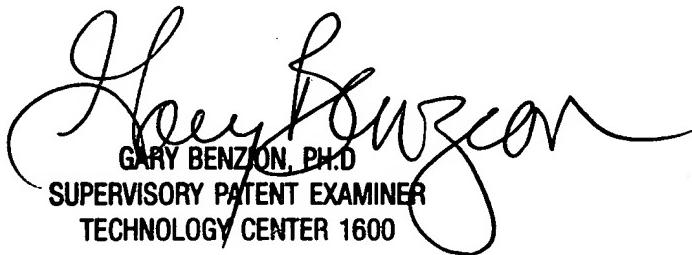
Art Unit: 1637

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday.,

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*SC*  
Suryaprabha Chunduru  
Examiner  
Art Unit 1637

  
GARY BENZION, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

*W*  
BJ FORMAN, PH.D.  
PRIMARY EXAMINER